

## REMARKS

### The Claimed Invention

The claimed invention is directed to methods for modifying fiber phenotype in a cotton plant, together with DNA sequences and constructs for use in the method and plant cells and plants produced using the method.

### The Pending Claims

Prior to entry of the above amendments, Claims 1-10, 12-16, 18-28, 30-39, 42-64 are pending. Claims 1-8, 28, 30-35, 42-50, 55-60 are directed to a DNA sequence. Claims 9-10, 36-37 and 51-52 are directed to a DNA construct. Claims 12, 38 and 53 are directed to a plant cell. Claims 13, 39 and 54 are directed to a plant. Claims 14-16, 18-22, 27 and 64 are directed to a method of modifying fiber phenotype in a cotton plant. Claims 23-24, 61 and 63 are directed to a recombinant DNA construct. Claims 25-26 and 62 are directed to an isolated DNA.

### The Office Action

Newly submitted claims 62 and 63 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 62 and 63 claim nucleotide sequences which are unrelated to those previously claimed.

The amendment filed September 28, 1999 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure.

Claims 1-10, 12, 13, 28, 30-39 and 42-60 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-10, 12-16, 18-21, 27, 28, 30-39, 42-60 and 64 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID Nos. 7, 11,

15 and any other promoters which may be obtained by hybridization with these promoters, does not reasonably provide enablement for all the claimed promoters.

Claims 1-10, 12-16, 18-21, 27, 28, 30-39, 42-60 and 64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

#### Amendments

Following the suggestion of the Examiner, Applicants have incorporated text from PCT/US96/09897 concerned with the Ltp promoter and plasmids pCGN5148, pCGN5149 and pCGN5616. Specifically:

Page 6, lines 21-23 of PCT/US96/09897 have been inserted into the specification on page 8, line 7.

Page 11, lines 4-6 of PCT/US96/09897 have been inserted into the specification on page 11, line 10.

Page 23, line 25 through page 25, line 15 of PCT/US96/09897 have been inserted into the specification on page 27, between lines 14-15.

Page 31, lines 20-26 of PCT/US96/09897 have been inserted into the specification on page 33, between lines 12-13.

Page 32, lines 9-19 of PCT/US96/09897 have been inserted into the specification on page 33, after line 20.

Page 37 line 1 through page 38, line 13; page 39 line 8 through page 40, line 24; and page 41 line 1 through page 42 line 2 of PCT/US96/09897 have been inserted into the specification on page 39 between lines 3-4.

Page 45, line 2 through page 48, line 7 of PCT/US96/09897 have been inserted into the specification on page 41 after line 26.

Minor typographical corrections have been made to pages 28-30 of the specification.

Following the Examiner's suggestion, Applicants have inserted the sequence listing as pages 43-70 of the specification.

Applicants also have canceled Claims 27, 43, 56, 58, 60 and 62-64, added new Claims 65 and 66, and have amended Claim 1, 14, 28, 35, 42, 44, 50, 55, 57 and 59.

Claim 1 has been amended to incorporate language according to the Examiner's suggestions. Support is found on page 9, lines 12-13 and lines 18-19, in Figure 5, and on page 34, lines 16-17.

Claim 14 was amended to recite "protein in a pigment biosynthesis pathway" because there was not appropriate antecedent basis in Claim 1 for "protein of interest". Support is found in originally filed Claim 15.

Claim 28 was amended to recite wherein said "transcriptional sequence is obtained by the method of probing a genomic library derived from a" plant fiber tissue. Support is found in Examples 1 and 2 on pages 27-32.

Claim 35 was amended to recite said "bacterial" gene for proper dependence from Claim 34. Support is found in originally filed Claim 8.

Claim 37 was amended to recite "cotton plant cell" for proper dependence from Claim 59. Support is found in originally filed Claim 15.

Claim 42 was amended to recite wherein said "transcriptional sequence is obtained by the method of probing a genomic library derived from a" plant fiber tissue. Support is found in Examples 1 and 2 on pages 27-32.

Claim 44 was amended following the Examiner's suggestion. "Cotton fiber cell" was changed to "cotton plant cell" because dependent Claim 52 recites wherein said "cotton plant cell is a cotton fiber cell". Support is found in originally filed Claim 15.

Claim 50 was amended to recite said "bacterial" gene for proper dependence from Claim 49. Support is found in originally filed Claim 8.

Claim 52 was amended to recite "cotton plant cell" for proper dependence from Claim 44. Support is found in originally filed Claim 15.

Claim 55 was amended to recite wherein said "transcriptional sequence is obtained by the method of probing a genomic library derived from a" plant fiber tissue. Support is found in Examples 1 and 2 on pages 27-32.

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Claim 57 was amended according to the Examiner's suggestion. Support is found on page 9, lines 12-13 and lines 18-19, in Figure 5, and on page 34, lines 16-17.

Claim 59 was amended according to the Examiner's suggestion. . "Cotton fiber cell" was changed to "cotton plant cell" because dependent Claim 37 recites wherein said "cotton plant cell is a cotton fiber cell". Support is found in originally filed Claim 15.

Support for new Claim 65 is found in originally filed Claim 27.

Support for new Claim 66 is found in originally filed Claim 28.

The above amendments are necessary to correct typographical errors, insert text from priority application PCT/US96/09897 to appropriately support originally filed Figures 7-13, and in carrying out the Examiner's suggestions to put the claims in form for allowance or in better form for appeal.

Applicants believe that no new matter has been added by any of these amendments and therefore respectfully request the Examiner to enter them.

#### Response

The Examiner's specific objections and rejections are reiterated below as small indented bold print, followed by Applicant's response in normal print.

#### Election Restriction

Newly submitted claims 62 and 63 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 62 and 63 claim nucleotide sequences which are unrelated to those previously claimed. A new search would be required for these independent and distinct inventions.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 62 and 63 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Furthermore, claims 1-10, 12-16, 18-22, 27, 28, 30-39, 42-59 and 64 will only be considered to the extent that they encompass sequences previously examined.

Claims 27, 43, 56, 58 and 62-64 have been canceled. As amended, Claims 1-10, 12-16, 18-22, 28, 30-39, 42, 44-55, 57 and 59 are not directly or indirectly concerned with

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either SEQ ID NO:16 or SEQ ID NO:17.

Objection to the Specification

The amendment filed September 28, 1999 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

The brief description of the drawings for Figures 7-13 includes terms which are not supported in the specification as filed, including "the Ltp promoter region from a cotton fiber specific lipid transfer protein gene," "pCGN5198," "pCGN5616," "pCGN5148," "pCGN5149." Furthermore, there is no disclosure in the specification as filed of the production of plants transformed with the cited constructs, so there is no support for "measurements" performed on these plants.

Applicants are required to cancel the new matter in the reply to this Office action. Alternatively, Applicants may wish to import into the specification portions of the disclosure of PCT/US96/09897, to which the instant application claims priority.

The computer readable form of the sequence listing submitted September 7, 1999 is in compliance with the requirements of 37 CFR 1.821 through 1.825. However, the paper copy of the sequence listing was not accompanied by an amendment directing that it be entered into the specification, and so it has not been entered.

Supporting text from PCT/US96/09897 that describes the Ltp promoter region and plasmids pCGN5148, pCGN5149 and pCGN5616 has been incorporated into the specification.

Please note that in the amendment submitted on September 28, 1999, reciting "pCGN5198" in the text for Figure 8 is incorrect. Only plasmids pCGN5149 and pCGN5616 are depicted in Figure 8. Please also note that the volume number for the reference citation to Bernan, *et al.* on page 37, line 6 of PCT/US96/09897 is incorrect, and that the journal name is missing. The correct citation is provided in the amendments to the specification above, and the abstract as it appears on Medline is attached to this response. As part of the amendments made to the specification, Applicants formally request with this response that the paper copy of the sequence listing submitted on September 7, 1999 to be inserted as pages 43-70.

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35 U.S.C. § 112, first paragraph

Written Description

Claims 1-10, 12, 13, 28, 30-39 and 42-60 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants are referred to the interim guidelines on written description published December 21, 1999 in the Federal Register at Volume 64, Number 244, pp. 71427-71440.

The claims are drawn to DNA constructs comprising a promoter sequence active in cotton fiber cells. However, the specification only discloses the 4-4-6 and rac13 promoter sequences isolated from cotton. In analyzing whether the written description requirement is met for genus claims, it is first determined whether a representative number of species have been described by their complete structure. In this case, the sequences provided in SEQ ID Nos. 7, 11 and 15 are the only species whose complete structure is disclosed (the promoter sequences within SEQ ID Nos. 7 and 11 are apparently identical). Next, then, it is determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics (i.e. other than nucleotide sequence). In this case, no additional information is provided, other than the biological activity Applicants hope will be possessed by promoters isolated by the recited method. In particular, the Rac9 promoter recited in claim 60 has not been disclosed. This limited information is not deemed sufficient to reasonably convey to one skilled in the art that Applicants were in possession of promoters besides those shown in SEQ ID Nos. 7, 11 and 15 at the time the application was filed. Thus it is concluded that the written description requirement is not satisfied for the claimed genus.

Applicants argue that the recitation of how the promoter sequences are to be isolated constitutes a description of the sequences themselves. This argument is not persuasive. Other than the disclosed embodiments noted above, Applicants have not provided a complete structure for any other promoter which could be isolated by screening a genomic library with cDNAs. No other identifying characteristics have been disclosed, nor is there any correlation between structure and the recited function.

Following the Examiner's suggestion, independent Claims 1, 44, 57 and 59 have been amended to recite a transcriptional factor selected from the group consisting of a) nucleotides 65-4163 of SEQ ID NO:7, b) SEQ ID NO:15, and c) a DNA sequence which hybridizes with nucleotides 65-4163 of SEQ ID NO:7 or SEQ ID NO:15. Claims 43, 56 and 58 are canceled. Applicants have made the amendments in the interest of furthering prosecution. Because the specification presents detailed disclosure of a method for identifying and isolating transcription initiation regions functional in a cotton fiber cell that the skilled artisan could readily apply to other rac and 4-4 sequences, or even other cotton fiber cell transcription initiation regions, Applicants respectfully submit for the record that the specification supports claims that are broader than the specific recitation of SEQ ID NO:7 and SEQ ID NO:15. Because

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the language of the claims has been duly amended to language that the Examiner has proposed as acceptable, Applicants respectfully request withdrawal of this rejection.

Enablement

Claims 1-10, 12-16, 18-21, 27, 28, 30-39, 42-60 and 64 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID Nos. 7, 11, 15 and any other promoters which may be obtained by hybridization with these promoters, does not reasonably provide enablement for all the claimed promoters. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims encompass promoters obtained from genomic clones of any plant species which hybridize under fairly low stringency conditions with coding sequences expressed in cotton fibers. One can not predict what will hybridize with the 4-4 and rac 13 cDNAs, particularly since no function is disclosed for the encoded proteins. Once a hybridizing genomic sequence is obtained, one must determine where the transcription start site is located (i.e. define the 3' end of the promoter). There is no simple method for determining the 5' end of the promoter, since promoter elements which control tissue specificity can be located hundreds of bases upstream of the transcription start site and Applicants have not identified any structural features of the disclosed promoters which cause expression in cotton fiber tissue. Thus the only way to determine whether a promoter construct is active in cotton fiber tissue is to produce transgenic plants containing the promoter construct. This is a large quantity of experimentation, even though (as Applicants argue) the skilled artisan knows how to perform the individual steps required. Furthermore, while Applicants argue that the claims only require that the promoter is to modify the phenotype of cotton fibers. One can not predict whether a promoter isolated by the recited method would be suitable for the claimed methods. A promoter which is "functional" at low levels, or only during a brief developmental stage, for example, would not be useful for the purposes contemplated in the specification. Finally, with regard to claim 44, the specification does not disclose any gene encoding an enzyme which degrades indigo or melanin.

For the reasons discussed above, it would require undue experimentation to make and use the full scope of the claimed invention. This is particularly true given the nature of the invention, the breadth of the claims, the amount of experimentation necessary and the unpredictable nature of the art.

For the purposes of furthering prosecution, independent Claims 1, 44, 57 and 59 have been amended according to the Examiner's suggestion to recite a transcriptional factor selected from the group consisting of a) nucleotides 65-4163 of SEQ ID NO:7, b) SEQ ID NO:15, and c) a DNA sequence which hybridizes with nucleotides 65-4163 of SEQ ID NO:7 or SEQ ID NO:15. Because the language of the claims has been amended to what the Examiner has proposed as acceptable, Applicants respectfully request withdrawal of this rejection.

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35 U.S.C. § 112, second paragraph

Claims 1-10, 12-16, 18-21, 27, 28, 30-39, 42-60 and 64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically:

Claims 1, 44, 57, 59 and 64 are indefinite and incorrect because some of the recited sequences are not cDNA.

Claim 64 is an improper dependent claim because it encompasses sequences not included in claim 1.

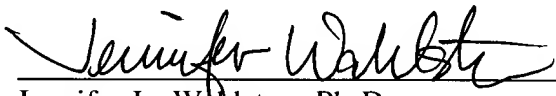
Claims 1, 44, 57 and 59 have been amended following the Examiner's suggestions, and therefore no longer recite "cDNA". Claim 64 has been canceled.

CONCLUSION

In view of the above amendment and remarks, it is submitted that this application is now ready for allowance. Early notice to that effect is solicited. If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned at (650) 328-4400.

Respectfully submitted,

Dated: 29 March, 2000

  
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